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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,983	STAUSS ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-42* is/are pending in the application.

4a) Of the above claim(s) *5 and 8-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 11/21/05 is acknowledged and has been entered.

2. Applicant is reminded of Applicant's election with traverse of Group I (claims 1-4, 6 and newly added claim 42), and species of SEQ ID NO: 1 containing peptide bonds in Applicant's response filed 2/2/05.

Claims 1-4, 6 and 42 read on the elected species, SEQ ID NO: 1, and are presently being examined.

The following are new grounds of rejection necessitated by Applicant's amendment filed 11/21/05.

3. Claims 1-4, 6 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The amendatory material not supported in the specification and claims as originally filed is as follows: "A peptide of 9 to 12 amino acid residues" recited in base claim 1. Applicant points to support (of record in the paragraph spanning pages 11-12 of the Applicant's amendment) in the specification on page 7 at line 21 and page 8 at lines 24-25. However, the disclosure is for "about 12" or "about 9" and "around 8 to 12, preferably 9", respectively.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 6 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is indefinite in the recitation of "wherein the variant contains one or two amino acid substitutions at positions 2 and 9" at the second to last line because it is not clear what is meant, *i.e.,* if the variant contains one substitution at each of positions 2 and 9, a substitution of one amino acid residue at each of positions 2 and 9 for two amino acid residues at each position, or a combination of both, and in addition, is the substitution at absolute position 2 or 9 of the FLYDVIAST peptide or the position 2 and/or 9 of the 10-12-mer peptide comprising FLYDVIAST.

b. Claim 4 is indefinite in the recitation of "which recognizes a cell which expresses a polypeptide comprising the the HLA-binding peptide of human CD45 polypeptide"

because it is not clear what is meant, *i.e.,* does the CTL recognize a cell that expresses a polypeptide comprising the FLYDVIAST peptide or a P2/P9, P2 or P9 variant peptide?

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-4, 6 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/26328 A1 (IDS reference) in view of The Leukocyte Antigen Fact Book (2nd edition, pages 244-247, 1997, IDS reference) and Rammensee et al (MHC Ligands and Peptide Motifs, LANDES Bioscience, Springer, NY, 1997, pages 217-227 and 236-281).

WO 97/26328 A1 teaches a method of treating a disease, including leukemia, comprising administering allo-restricted allogeneic CTL specific for peptides from self proteins that are expressed in tumors and in a limited number of normal cells, tissue-specific differentiation antigens, and in the case of leukemia, CTL with specificity for leukemias can be generated against peptides that are expressed in leukemic cells but not in cells outside the hematopoietic lineage and then used for adoptive immunotherapy of leukemia patients where they will eliminate leukemic cells and possibly some normal bone marrow derived cells. WO 97/26328 A1 teaches that possible loss of normal bone marrow cells is not expected to cause any problems because these patients are frequently treated with bone marrow transplantation from healthy donors (see entire article, especially page 19 at lines 21-30 and continuing onto page 20 at lines 1-5 and page 23 at lines 11-19). WO 97/26328 A1 further teaches that known CTL epitope peptides or newly identified peptides may be used, in the latter instance, the peptides that bind to a particular HLA class I molecule may be identified and may represent better targets for adoptive immunotherapy since they are likely to be subdominant peptides that are less likely to be immunoselected by the patient's CTL responses. WO 97/26328 A1 teaches methods for generating said CTL, and that the stimulator cell has a type of HLA class I molecule that is not present on the healthy individual's cells, and further teaches testing of binding to HLA class I molecules and for generating and stimulating CTL. WO 97/26328 A1 teaches that HLA-A0201 is particularly preferred allele that is present on the stimulator cells at a high frequency in the human population (page 27 at lines 19-30 and page 28 at line 1).

WO 97/26328 A1 does not teach the CD45 peptides recited in the instant claims 1-4, 6 and 42 that consist of or comprise SEQ ID NO: 1.

The Leukocyte Antigen Fact Book teaches that CD45 protein(s) are found on all cells of hematopoietic origin, except erythrocytes, and further teaches the amino acid sequence of the human CD45 protein and that it is 1281 amino acid residues in length.

Rammensee et al teach anchor residue motifs for peptides that bind to individual class I MHC molecules (HLA in humans) including HLA-A0201, and that most peptides that bind class I molecules are between 8 and 11 amino acid residues in length consonant with the length of peptide required to span the class I MHC binding groove. Rammensee et al teach methods of predicting MHC class I peptide epitopes using motifs to identify subsequences possessing the motif in proteins of interest. Rammensee et al teach that the motif for peptides that bind to HLA-A0201 is L or M at position 2 of the peptide and V or L at the carboxy-terminal position of the peptide, but that other endogenous peptides as well as CTL epitope peptides that bind to HLA-A0201 may have I, T, M or A at position 2 as well, and A, I, T, S or C at the carboxy-terminus. Rammensee et al teach that most peptides that bind to HLA-A0201 are 9 to 10 amino acid residues in length (pages 271-227 and 236-281).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made peptides as per the teaching of Rammensee et al (see below) from the CD45 human protein taught by The Leukocyte Antigen Fact Book in the method taught by WO 97/26328 A1 for use in generating allo-restricted CTL with specificity for peptides that are expressed in leukemic cells but not in cells outside the hematopoietic lineage and said allo-restricted CTL used for adoptive immunotherapy of leukemia patients.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because WO 97/26328 A1 teaches that allo-restricted CTL that are specific for peptides that are expressed on leukemic cells but not in cells outside the hematopoietic lineage are useful to treat patients with leukemia and that such a use is not expected to cause any problems due to possible loss of normal bone marrow cells because these patients are frequently treated with bone marrow transplantation from healthy donors, and The Leukocyte Antigen Fact Book teaches that the human CD45 protein is found on all cells of hematopoietic origin.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the method of epitope prediction taught by Rammensee et al using the peptide binding motif of a frequently expressed HLA molecule such as HLA-A0201 to scan the human CD45 protein sequence taught by The Leukocyte Antigen Fact Book for subsequences that would potentially bind to HLA-A0201 and function to stimulate CTL as taught by Rammensee et al and by WO 97/26328 A1, in effect to generate peptides of 9 amino acid residues in length that would be predicted to bind to HLA-A0201 from the sequence of human CD45 protein, said peptides having the motif anchor residues at positions 2 and 9 or 10, and to have produced the peptides recited in the instant claims comprising or consisting of SEQ ID NO: 1 which is a subsequences of human CD45 that has the anchor residues taught by Rammensee et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to generate peptides as per the teaching of Rammensee et al using the human CD45 protein sequence taught by The Leukocyte Antigen Fact Book to use in the method taught by WO 97/26328 A1 of identifying peptides that can bind to alleles present in high frequency in the population such as HLA-A0201 for generation of allo-restricted CTL that are useful in treating leukemia patients.

Applicant's arguments have been fully considered, but are not persuasive.

Applicant's arguments are of record in Applicant's said amendment on pages 17-23 under the section entitled "Rejection Under 35 U.S.C. 103." It is Applicant's position that: (1) none of the references alone or in combination disclose or suggest a peptide of 9-12 amino acid residues in length, wherein the peptide contains the sequence of SEQ ID NO: 1, or position 2 and/or position 9 variant thereof, (2) none of the references provide the motivation to combine said references, (3) the WO document does not disclose CD45 as being a suitable target for tumor immunotherapy, (4) the instant specification discloses on page 2 at lines 18-19 that CD45 is expressed in hematopoietic malignancies at similar levels as expressed on normal cells and the WO document discloses that the antigen for the CTL is expressed abnormally, so there would not exist motivation to combine the references, (5) the references do not provide a reasonable expectation of success, (6) predictive methods do not always predict actual binding affinity so there is no way of knowing based on the Rammensee reference whether any CD45 peptides generated through their method would bind an HLA molecule, (7) Applicant inserted the CD45 sequence into a web-based algorithm based on Rammensee to search for 10-mer peptides that bind to HLA-0201 which generated a list of hundreds of peptides without guidance for which would bind, (7) Rammensee does not provide a reasonable expectation of success for peptides with binding affinity that are also immunogenic, but Applicant experimentally generated immunogenic peptides from CD45, (8) Fikes discloses epitopes of an antigen that is not CD45, and so does not provide a reasonable expectation of success for which peptides of CD45 bind and are immunogenic.

It is the Examiner's position that: (1) the references are being argued separately, (2) that the motivation to combine references is provided by the teaching of the WO document that CTL with specificity for leukemias can be generated against peptides that are expressed in leukemic cells, but not in cells outside the hematopoietic lineage, such peptides deriving from "self proteins that are expressed in tumors and in a limited number of normal cells (tissue-specific differentiation antigens)", "tissue-specific proteins that are expressed in tumors", "CTL with specificity for leukaemias can be generated against peptides which are expressed in leukaemic cells but not in cells outside the haematopoietic lineage", and target proteins such as "WT-1" and "GATA-1," combined with the teaching of the Human Leukocyte Handbook that CD45 is a protein with expression limited to cells of hematopoietic lineage except for erythrocytes,

(3) and (4) the WO document discloses suitable target proteins for treatment of leukemia such as WT-1 and GATA-1 (which are disclose in Applicant's specification on pages 1-2 to be suitable targets for CTL against leukemia, said proteins being expressed on normal cells), *i.e.,* they are expressed on cells of the hematopoeitic lineage, and although the WO document discloses classes of target proteins such as those expressed abnormally on tumor cells, it also discloses using differentiation antigens of the hematopoietic lineage that are also expressed on leukemic cells, and the Human Leukocyte Handbook discloses that CD45 is such a differentiation antigen, so the motivation to combine references exists, (5) and (6) the instant claims are not drawn to a method of predicting peptides that bind to an HLA molecule and elicit a CTL response, but rather to a product that is capable of binding to HLA-A0201 and eliciting a CTL response; the combined references provide motivation to make a nonamer peptide that is a subsequence of CD45 protein with L2/T9 anchor residues with the expectation that it might bind to HLA-A2. It is an inherent property of the FLYDVIAST that it binds to HLA-A2 and elicits a CTL response, (7) the claimed peptide is a 9-mer not a 10-mer peptide, the portion of Rammensee et al that was cited by the Examiner teaches using primary anchor residues to predict HLA binding peptides, although non-cited portions of the book do contain teaching of using computer based algorithms incorporating use of secondary anchor residues and knowledge of deleterious residues at other positions, such as the web-based algorithm used by Applicant, and the web-based algorithm does provide a ranking of those peptides most likely to bind; however, these are side-issues. The teaching of using primary anchor residues to predict binding peptides in combination with the other cited references provides motivation to make the FLYDVIAST peptide because it might bind to HLA-A2 since it has anchor residues, and it is not required that the references provide a teaching for predicting which peptides are immunogenic since the instant claims are not drawn to a method for predicting binding peptides and immunogenicity, (8) Fikes et al (U.S. Patent No. 6,602,510 B1) is being argued separately by Applicant, and is not of record in the instant rejection. In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. Claims 1-4, 6 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/26328 A1 (IDS reference) in view of The Leukocyte Antigen Fact Book (2nd edition, pages 244-247, 1997, IDS reference), LANDES Bioscience, Springer, NY, 1997, pages 217-227 and 236-281) and U.S. Patent No. 6,602,510 B1.

WO 97/26328 A1 teaches a method of treating a disease, including leukemia, comprising administering allo-restricted allogeneic CTL specific for peptides from self proteins that are expressed in tumors and in a limited number of normal cells, tissue-specific differentiation antigens, and in the case of leukemia, CTL with specificity for leukemias can be generated against peptides that are expressed in leukemic cells but not in cells outside the hematopoietic lineage and then used for adoptive immunotherapy of leukemia patients where they will eliminate leukemic cells and possibly some normal bone marrow derived cells. WO 97/26328 A1 teaches that possible loss of normal bone marrow cells is not expected to cause any problems because these patients are frequently treated with bone marrow transplantation from healthy donors (see entire article, especially page 19 at lines 21-30 and continuing onto page 20 at lines 1-5 and page 23 at lines 11-19). WO 97/26328 A1 further teaches that known CTL epitope peptides or newly identified peptides may be used, in the latter instance, the peptides that bind to a particular HLA class I molecule may be identified and may represent better targets for adoptive immunotherapy since they are likely to be subdominant peptides that are less likely to be immunoselected by the patient's CTL responses. WO 97/26328 A1 teaches methods for generating said CTL, and that the stimulator cell has a type of HLA class I molecule that is not present on the healthy individual's cells, and further teaches testing of binding to HLA class I molecules and for generating and stimulating CTL. WO 97/26328 A1 teaches that HLA-A0201 is particularly preferred allele that is present on the stimulator cells at a high frequency in the human population (page 27 at lines 19-30 and page 28 at line 1).

WO 97/26328 A1 does not teach the CD45 peptides recited in the instant claims 1-4, 6 and 42.

The Leukocyte Antigen Fact Book teaches that CD45 protein(s) are found on all cells of hematopoietic origin, except erythrocytes, and further teaches the amino acid sequence of the human CD45 protein and that it is 1281 amino acid residues in length.

U.S. Patent No. 6,602,510 B1 discloses that peptides that bind to HLA class I molecules are about 8 to about 13 amino acid residues in length and possess amino acid residues at certain positions in the peptide sequence that are required for allele-specific binding. U.S. Patent No. 6,602,510 B1 discloses that a supertype motif is a peptide binding specificity shared by HLA molecules encoded by two or more HLA alleles, and that vaccines which bind to HLA supertypes such as A2, A3 and B7 will afford broad, non-ethnically biased population coverage. U.S. Patent No. 6,602,510 B1 discloses that the HLA-A2 supermotif is L, I, V, M, A, T or Q at position 2 of the peptide, and I, V, M, A, T or L at the carboxy-terminus of the peptide. U.S. Patent No. 6,602,510 B1 discloses

that 9-mer subsequences of tumor-associated antigenic proteins were scanned to identify potential HLA-A2 supertype allele binding peptides, *i.e.,* that would bind to HLA-A0201 as well as other alleles in the supertype (especially column 18 at lines 34, column 2 at lines 58-column 3 at lines 1-3, column 13 at lines 11-15, Table 2 and 2A, Table 4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made the peptides as per the disclosure of U.S. Patent No. 6,602,510 B1 (see below) from the CD45 human protein taught by The Leukocyte Antigen Fact Book for use in the method taught by WO 97/26328 A1 for generating allo-restricted CTL with specificity for peptides that are expressed in leukemic cells but not in cells outside the hematopoietic lineage and said allo-restricted CTL used for adoptive immunotherapy of leukemia patients.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because WO 97/26328 A1 teaches that allo-restricted CTL that are specific for peptides that are expressed on leukemic cells but not in cells outside the hematopoietic lineage are useful to treat patients with leukemia and that such a use is not expected to cause any problems due to possible loss of normal bone marrow cells because these patients are frequently treated with bone marrow transplantation from healthy donors, and The Leukocyte Antigen Fact Book teaches that the human CD45 protein is found on all cells of hematopoietic origin,.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the method of epitope prediction disclosed by U.S. Patent No. 6,602,510 B1 using the peptide binding motif of a frequently expressed HLA molecule such as HLA-A0201 to scan the human CD45 protein sequence taught by The Leukocyte Antigen Fact Book for subsequences that would potentially bind to HLA-A0201 and function to stimulate CTL as disclosed by U.S. Patent No. 6,602,510 B1 and as taught by WO 97/26328 A1, in effect to generate peptides of 9 or 10 amino acid residues in length that would be predicted to bind to HLA-A0201 from the sequence of human CD45 protein, said peptides having the motif anchor residues at positions 2 and 9 or 10, and to have produced the peptides recited in the instant claims comprising or consisting of SEQ ID NO: 1 which is a subsequences of human CD45 that has the anchor residues disclosed by U.S. Patent No. 6,602,510 B1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to generate peptides as per the disclosure of U.S. Patent No. 6,602,510 B1 using the human CD45 protein sequence taught by The Leukocyte Antigen Fact Book to use in the method taught by WO 97/26328 A1 of identifying peptides that can bind to alleles present in high frequency in the population such as HLA-A0201 for generation of allo-restricted CTL that are useful in treating leukemia patients.

Applicant's arguments have been fully considered, but are not persuasive.

Applicant's arguments are of record in Applicant's said amendment on pages 17-23 under the section entitled "Rejection Under 35 U.S.C. 103."

The Examiner's position enunciated supra at item #7 of this Office Action apply herein, except that Rammensee was not cited in the instant rejection, and Fikes et al is not required to provide absolute certainty for which predicted peptides would bind to an HLA molecule and be immunogenic because the combined references provide motivation to make the FLYDVIAST peptide for the reasons of record in the instant rejection, and the instant claims are drawn to a peptide, not to a method of assuring which peptides bind HLA-A0201 and are immunogenic. The recited properties of binding to HLA-A0201 and being capable of eliciting CTL are inherent properties of the art peptide.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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